EXHIBIT 146

From: Wanda Eng
Sent: Thursday, April 17, 2008 10:24 PM
To: Phyllis Lambridis <PLambridis@actavis.com>
Cc: Wanda Eng <WENG@actavis.com>
Subject: Totowa Potential 483 items and comments

Potential 483 items

- The Quality Unit has released batches of drug products that failed their specifications. For example
- Failure to file prior approval supplement for site transfer of the laboratory and manufacturing of drug products from the Little Falls facility to the Riverview facility. The laboratory at Riverview was used to test finished products which were distributed. The drug product, Digoxin, was manufactured at the Riverview facility. _____lots of Digoxin have been distributed.
- The Quality Unit
  - Failed to adequately conduct deviation investigations in that the route cause was not determined, no impact assessment on other batches and products and deviations were not closed in a timely manner. For example:
  - Failed to file NDA Field Alerts (this is a repeat observation) and failure to file them within the required time period of within 3 working days after discovery. Confirmed stability failures were not filed. For example:
  - Failed to reject products which did not meet in-process and finished product specifications. For example:
- Change controls were inadequate in that they do not describe why the change is necessary and they are not linked with deviation investigations
- The Quality Unit released products for distribution prior to the completion of the deviation investigation. For example:
- Continue to manufacture and ship unapproved DESI drug products after receipt of a Warning Letter requesting justification to market the products.
- Failure to have an adequate stability programs.
  - Stability sample not tested at test intervals. For example
  - Stability samples not tested within the time intervals of within 30 days. For example
  - Stability samples were not placed in the stability chambers in a timely manner
    1. Several products were not placed on stability in 2007
    2. wrong lot placed on stability
  - There is no complete inventory of the products in the stability chambers
  - Pulled wrong strength for stability testing
  - Stability samples were found in the DEA stability chamber which were not supposed to be in there.
  - Stability chamber _____has a defective humidity sensor and no product impact assessment was made
  - Stability chambers are not alarmed
- Laboratory investigations of OOSs were inadequate
  - Laboratory OOSs were determined to be analyst error & sampling error without adequate justification
  - Methods are not validated
    1. impurity methods not stability indicating
  - Calculation errors were found which included:
  -
- Failure to have adequate PM program for the tableting punches. (punches are not measured after each batch; metal shavings are found; tablets were found thin, double & triple in size)
- Failure to adequately investigate impact on products when there are scale calibration failures, humidity sensor failure, hardness tester calibration failure, pressure gauge leaking and temperature excursions. For example:
- Use of work orders for equipment failures when using change control is necessary which are handled by the Quality Unit
  - No impact assessment of batches made prior to the equipment failure
- Filings submitted to FDA to widen specs when a product fails to meet spec.
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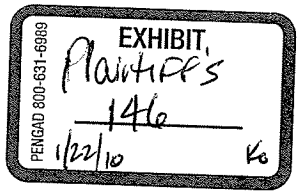

Comments:

- Many manufacturing processes are invalidated by the high percentage of stability failures
- Why were the stability failures found recently?
- Why so many NDA Field Alerts filed within the last months?

- Stability issues:
  - Formulation problems; incompatibility of ingredients
  - Blend uniformity problems, not homogeneous; [redacted]
  - Don't know if true stability problem
- Don't check or replace worn equipment; no PM program for tableting punches
  - Metal shavings found on tablets
  - Screws found with tablets
- Digoxin, a toxic product with double, triple and thin tablets; lots were not rejected; partial lot releases
- Black spots found on tablets
- Impact on products when moving to ICH conditions
- Filing status of ICH conditions?
- Failure to adequately test vitamin products in that not all labeled ingredients are tested
- Filings submitted to FDA to widen specs when a product fails to meet spec.
  - Specs were filed for the finished product, but, forgot to widen for the stability test specs
- FDA statements:
  - OUT OF CONTROL
  - LACK OF RESOURCES
  - LACK OF EXPERTISE
- Quality unit failed to do its job
- Release of products in interstate commerce which did not meet filed ANDA specifications
- Testing into compliance; retesting without justification
- Failure to file NDA Field Alerts for stability failures, especially 24 months failures

Statements/questions during wrap up calls

- Scott asked : Why do we have to report 24 month stability failures when the product has expired?
- During one of the visits to the FDA regarding the site transfer to Riverview, Scott stated that Compliance Officer, Andrew Ciacchia said that if they use the laboratory at Riverview, they would be using it at risk.